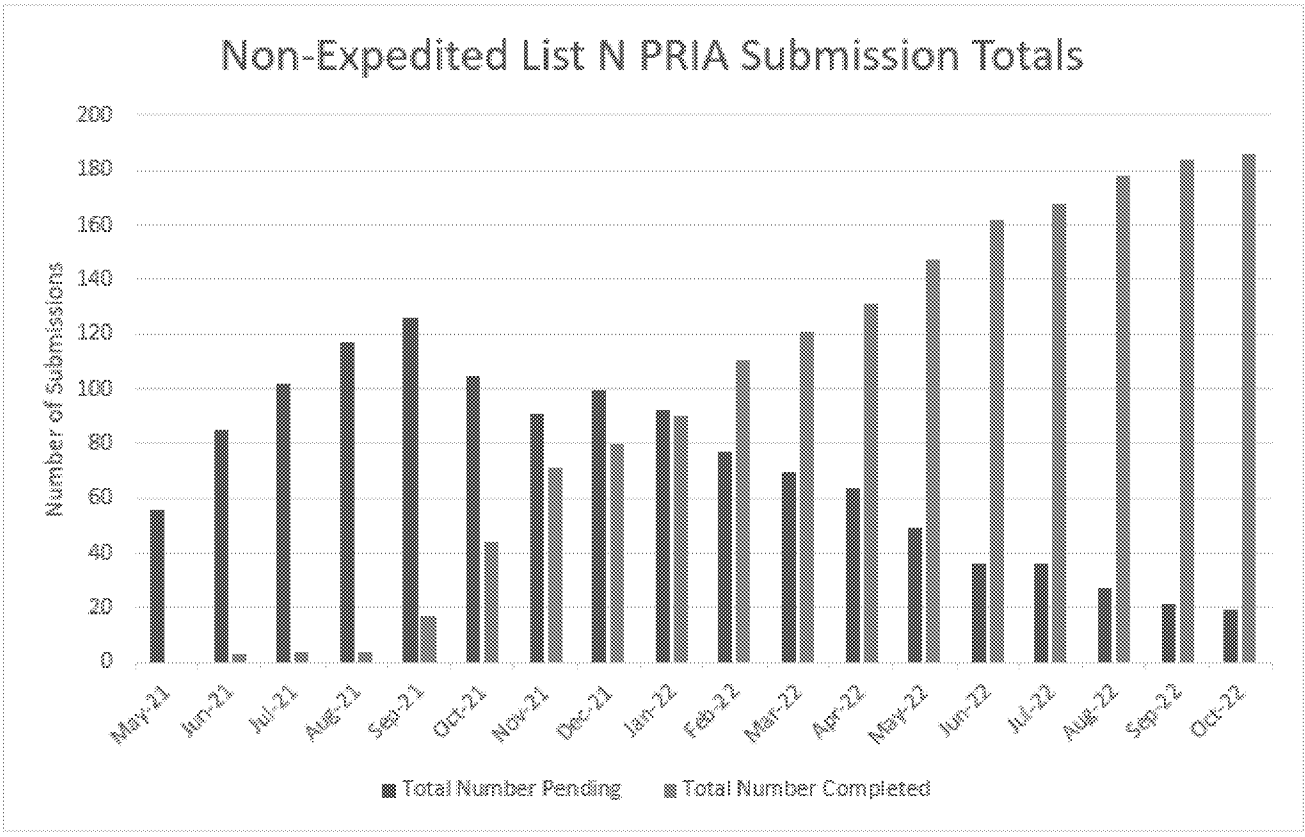
OPP GENERAL WITH AD
November 1, 2022

Coronavirus (COVID-19)

- COVID stats



- **List N updates** – as of 10/25/22:
    - 629 List N products (13 products removed as compared to last month; 4 had efficacy failures, one was a duplicate, and 8 were cancelled)
    - 6 products added and 5 qualify for List Q (EVP)
    - No new variant claims

Novel pending Section 3 submissions (and pre-submission discussions) – no updates

- Kraton – Biaxim. 3/1 meeting to discuss S3 new a.i. registration. Asking for modifications to the efficacy protocol. They haven't initiated testing yet. Submission to include TGAI, MUP, and EUP.
- Reckitt – Honeycake air sanitizer/treatment (dipropylene glycol a.i. – new use); Lysol brand name
    - Registered on 9/30/22
    - Allowed phage to be used as surrogate virus (for the first time)
    - Getting complaints from other companies
- Honeywell Antiviral Fiber for HVAC Filters for SARS-CoV-2 – no update
    - TX and NC S18 applications withdrawn.
    - AD met w Honeywell on 11/4/21 to discuss testing methods/data requirements for Section 3 submission. They need to submit a protocol.
    - They have currently submitted a device determination

- **Section 18s:**
    - **Grignard - Clearburst** (approved in GA, TN, NV, PA, TX, VA, MD)

- RD granted approval in VA and renewed in PA, TN, and TX for one yr to Jan 2023
- **AD is meeting w Grignard next week to discuss how application equipment and room sizes may impact the design of an efficacy study**
- Grignard has approached all states about renewing for another year to Jan 2024
- Team has met w states to determine actual use (very limited to TN – Amtrak testing; GA – use in one state; and PA – pending contract; other states not interested
- Initial recommendation not to renew –
    - COVID is no longer an emergency
    - Grignard has had ample to time to generate necessary data/protocols and pursue Section 3 registration path
    - They have hired a new consultant – SRC.

- RD was approached by a company with a treated filter for a potential S18 in RI. The a.i. would be nanosilver and require a new a.i. registration

Efficacy test methods development – no updates

- Air treatments
    - Chemical treatments: Will issue minimum testing requirements and guidance for products applied directly to air by the end of calendar year 2022. Tajah Blackburn is AD's lead.
        - Draft guidance is for unoccupied spaces
        - May separate into two product types: 1) bug bomb release OR 2) HVAC system release.
            - For HVAC system use, may take longer to release; want to require both lab based efficacy data on surfaces and in-field verification testing
    - Filter treatments: When we met w NIOSH/CDC in March, they emphasized that based on the mechanism of action of a treated filter, anything getting through the filter, isn't going to be impacted by the a.i.; treated filters unlikely to reduce pathogens in air beyond untreated filters. There may be some additional benefit on the filter (i.e., may help with mold and mildew on filters); CDC is recommending against PH claims on filters
        - Based on discussion w ORD WG, we are developing a position paper to evaluate the relationship between treated filters and airborne exposure
        - Given challenges w selection of appropriate filter (treated and non-treated) for testing and ORD follow up testing; project deadline likely to extend beyond end of FY22.
        - Finalizing selection of filters for testing at ORD. Planning on using a citric acid treated and untreated filter and perhaps a second a.i. (graphene).
        - We have identified the test conditions (i.e., temp, humidity, soil, filter placement) for first testing
- Residual efficacy test methods
    - Done!

Change in policy for sanitizer viral claims – no updates

- Briefed Michal on 2/23
- Option 3: Proceed with guidance and solicit public comment (short term) and pursue rulemaking (long term); include time-limited registration; benefits: EJ, lower concentration of chemicals, supply chain
- EB has developed a draft FRN
- Kristen Willis participated in July 5th IRG meeting and provided update
    - Discussing term or time limited registration (5 yrs?) and when it begins (e.g., at time of first product registration or posting of final guidance); industry wants 5 yrs from date of registration or 7 from activation of policy (need state approval)
- Team is working through OGC comments

List Updates

- **Updated lists for TB, norovirus, and C. diff - will be modernized (similar to List N) by the end of 2022.**

Devices and Enforcement

- **R9 offer of 2 FTE for devices rulemaking support**
  - **Developed a list of activities, milestones, timing, and FTE (including coordination w other Divisions) needed to pursue devices rulemaking – NOT INCLUDING FTE NEEDED FOR IMPLEMENTATION**
  - **Revised paper incorporates feedback from OECA and OGC**
  - **11/3 meeting w Michal and Jake to discuss**
- **Yvette Hopkins (co-chair of DDWG) retiring in December – need a replacement preferably outside AD; note from J. Mosby asking OPP to transition all of Yvette's responsibilities including FIFRA enforcement and jurisdictional liaison to OPP. Diane Isbell also retiring in Dec!**
- **Hal Ambuter and Lisa D. met w Royan on October 4th to discuss importation of R&D samples (and a TSCA approach for R&D samples)**
- OCSPP personnel participate in two work groups on UV lights. One was formed by the Office of Science and Technology Policy (OSTP) within the White House. The other group was formed by the in the National Academies of Science. The focus is on the potential use of UV light for COVID-19 and future pandemics. OSTP has prioritized "innovations to improve indoor air quality and to reduce disease transmission in buildings" including pesticide devices like germicidal UV as a key part of its pandemic preparedness strategy as outlined in the [HYPERLINK "https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whitehouse.gov%2Fwp-content%2Fuploads%2F2022%2F07%2FM-22-15.pdf&data=05%7C01%7CIsbell.Diane%40epa.gov%7C9ef3d5d18e854185fc1208daa63f57f6%7C88b378b367484867acf976aacbeca6a7%7C0%7C0%7C638005091150870881%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=lGVkA0jJOG8fD39deWrHRiHqFUoRLnMSma3V%2B7Tetm8%3D&reserved=0"]. In addition, OSTP has outlined in a [HYPERLINK "https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.whitehouse.gov%2Fwp-content%2Fuploads%2F2022%2F09%2F09-2022-AP3-FIRST-ANNUAL-REPORT-ON-PROGRESS.pdf&data=05%7C01%7CIsbell.Diane%40epa.gov%7C9ef3d5d18e854185fc1208daa63f57f6%7C88b378b367484867acf976aacbeca6a7%7C0%7C0%7C638005091150870881%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Pebd1gZVgAR2U2BWzg5c61Ju07vBBIjDsodtbGMQY94%3D&reserved=0"] the importance of clear standards and guidance for expanding the use of GUV technologies and developing standard efficacy testing methods for air treatment technologies writ large (pg 26).
- AD/DDWG is working with OECA, OGC and OPS on a **new compliance advisory on devices** as well as a document on false and misleading claims for devices for use by EPA regional offices. **- NO CHANGE**
  - The compliance advisory will be added to the website with other existing compliance advisories.
    - A draft of the compliance advisory is being reviewed by the Office of Compliance OD.
  - Will work with the OPS Comms team to announce the availability.
- AD/DDWG is also working with OECA, OGC and OPS on a **device claims document** – **NO CHANGE**
  - Should reduce the inquiries that the DDWG receives from regional offices on claims.
  - Review process is anticipated to start soon.
- Update of **device webpages** – **NO CHANGE**
  - DDWG is in the process of revising the Device Guide for Consumers and the Registration Manual Chapter 13 on devices to include information on new types of devices seen during the pandemic as well as clarify information on use of ozonated water in food handling establishments.
  - DDWG started its review; Will work with the OPS Comms team to issue an OPP update when these webpages are updated.
- **Coalition Letter (9/30/22) on modernizing FIFRA Compliance for Water Filtration Systems**

- From Water Quality Ass. (WQA) and Int. Ass. Of Plumbing and Mechanical Officials (IAPMO)
- Meeting request to discuss proposal for alternative compliance pathway for manufacturers
- Reliance on 3rd party certification standards (e.g., NSF/ANSI)
- Covers pesticides (treated article exemption) and pesticidal devices (ANSI standards to cover performance/claims)
- AD met with OGC and OECA on 10/25 to evaluate the recommendations outlined in the coalition letter. AS a follow up, AD reached out to OW to assess if the collation issues are widespread and of concern to OW. OW noted their AA Radika Fox was cc'd on the coalition letter.
- OW indicated that they are not aware that this is a problem and they have not had other drinking water organizations reach out with concerns.
- We are planning a follow up meeting (TBD) with AD, OW, OECA and OGC to develop a response.

- **OAR's Indoor Environments Division (IED) Request for Information (RFI)**
  - 10/5/22 FRN includes a 60-day comment period requesting input on actions that lead to improvements in indoor air quality (IAQ) in the nation's building stock to help mitigate disease transmission (e.g., COVID-19).
  - Actions include ventilation, filtration, and *air cleaning* improvements
  - HCPA contacted AD with questions about the relationship of the RFI to antimicrobial pesticide products
  - We requested a meeting with IED Director to get more info since were not aware of the RFI until recently

ETO (new timeline)

- EtO timeline - push from WH to release by end of calendar year
  - Nov. 2-9: AD/HED addressing OD/DD comments on the DRA addendum
  - Nov. 4: FAR review of OAR rulemaking
  - Nov. 7- Nov 14: Series of briefings (PADs, Ras, and WH) requested by OPA to pre-empt any issues raised by FDA re: supply chain (high level, small group to discuss risk assessment results, proposed mitigation, industry challenges, and planned outreach). Working on TPs for briefings – no slides.
  - Nov. 9-16: OCSPP AA review of DRA Addendum – Michal – anyone else?
  - Nov. 14-16: FDA and OSHA review of relevant PID sections
  - Nov. 28: Start of routing PID for review (3 weeks) ending w AA review
  - Dec 1-2: OAR proposed rule to OMB; WH asking OMB for expedited review (includes interagency review); unclear if OMB is committed to an expedited timeframe
  - Dec. 16: Sign the PID
  - Community meetings: Recent meeting in R4, Memphis where there is strong community effort to shut down the facility (leased); alerted FDA during the interagency EtO TF call that there could be supply chain issues if the facility is shut down.
  - Erika Sasser (Director of the Health and Environmental Impacts Division in OAQPS) is the new OAR contact

Pentachlorophenol Cancellation and Issue w Disposal vs. Resuse of "final treatment" solutions

- August 25, 2022 letter from Jeff Miller of the Treated Wood Council
- Final decision states that unused penta must be disposed of in compliance w RCRA hazardous waste disposal requirements; the TWC wants to discuss options for transferring "final treatment" solutions generated at one site to other end-user sites to consolidate to a volume that can be reused for wood treatment purposes – seeking to use valuable product during the phase out period rather than discard (which is "unnecessarily wasteful of valuable commodity, costly, and would raise capacity issues for incinerators and landfills").
- Estimate 580K to 1.16M gallons of penta work solution will remain; disposal cost ranging from $5.8-11.6M (assuming $10/Gallon)

- Final treatment solutions are "unregistered pesticides"
- Options:
    - Permit transfer of leftover wood preservative under custom blending policy
    - List as hazardous waste that could be recycled in accordance w 40 CFR Section 261.1
    - Publish guidance that allows the transfer and reuse
    - Initiate rulemaking to clarify existing regulations – narrow scope
- OECA, OGC, OPP stance – no viable options under which unregistered pesticides can be transferred for use. Enforcement discretion w issuance of No Action Assurance – would need a request from the program office with bridge to a rule that would render the unlawful activity lawful in the near future and a demonstration that such discretion is in the public's interest.
- Will rework options paper to include input from OGC on new options to allow distribution as part of terms of cancellation notice and register the penta solution as a pesticide

ESA

- Met w Jake today to debrief him on AD stakeholder concerns
- AD is working on a presentation (for EFED, then Services) on our chemicals/use patterns, challenges, and strategy to get NLAA concurrence for a subset of cases

FY23 Priorities

- AD management met on 9/15 to discuss FY23 priorities; will follow-up w "must dos", "need more resources to do" and "low priority"

CBC letter on non-PRIA backlog

- 9/9/22 letter from CBC about non-PRIA backlog and intention to deprioritize these actions in FY23
    - Business critical; problematic for registrants; imposed costs and impaired their ability to manage product supply and meet customer obligations
    - Asking for us to recognize importance and reconsider prioritization
- **AD strategy to close out older notifications**
    - **Close out all non-PRIA notifications submitted prior to FY20; give registrants 30 days to communicate whether they would like to keep any of these older actions open; OPP Update and trade meetings to communicate; onus on registrant to provide the information**
    - **Current non-PRIA notification backlog is 2,443 actions; proposal would close out ~1,500 actions leaving 850 actions remaining**
    - **After 60 days, companies may proceed w the labeling changes; typically AD confirms unreviewed notification changes when products come in for additional label amendments**
    - **Will meet informally w a subset of states to get their reaction before taking to SFIREG (closed door session)**

Rulemaking re: comparative safety claims at 40 CFR Part 156.10 – no updates

- To address DfE logo concerns from OGC
- Allow "free from" claims (e.g., bleach free, DEET free) – **In interim, we will allow phosphate-free claims and address bleach-free claims as we have been (allowed for laundry products or for Clorox)**
- **HCPA/CBC request for a meeting with Ed on "free-from" label claims (RD and AD)**
- Resources are a major concern – RD concurs
    - Contractor support will be necessary for economic (including small business), EJ and children's health impact analysis. It would also be helpful to have contractor support for federalism and tribal consultations.

Proposed new labeling mitigation for treated seed

- Proposed labeling of neonicotinoid treated seed will likely have consistency concerns regarding current antimicrobial pesticide treated articles that do not require any product labels or identification (e.g., treated fabrics, impregnated plastics, etc.)

Personnel/hiring – currently have 79 onboard FTEs + 11 NOWCCs (including details in/out and Rose and John's departure)

- BC backfill for Reevaluation branch
  - Eric Miederhoff
- Acting BC backfill for RMB1 (to replace John Hebert)
  - Donna Kamerei and Meg Hathaway
- Backfill Reevaluation Branch GS-14 TL was change to a GS-14 Senior EPS (to focus on label mitigation)
  - Finalizing announcement now
- Tim McMahon (AD's last of 3 GS-15 Senior Science Advisor) planning on retiring at end of December 2022; we have not been able to backfill the other 2 vacancies (Tim Leighton and Laura Parsons) – DDs agreed to backfill at 9/29 resources meeting - options? Toxicologist is a critical need for AD!
- Diane Isbell retiring at the end of December 2022. DDWG – will need 2 new co-chairs
- Kay Montague retiring at the end of March 2023
- AD's 2 new FTEs
  - Will hire one reviewer for RMB2/Team 34 and one CRM for Re-evaluation – both are necessary to justify TL backfills in both branches; changed initial position to bring on another toxicologist
    - Areej Jahangir (Schedule A) for AD/RB; 10/10/22 start date
    - RAB8 hires – keep structure and realign – waiting on next steps per resources meeting
- AD's TL hires
  - RMB2 – Marcel Howard officially started as the permanent Team 34 TL
  - RMB1 –Tara Flint selected for PM detail – make permanent given selection of Eric M. who previously occupied the PM TL; Aline Heffernan to RMB1 for the one-yr detail (to meet minimum team size requirement)
  - RMB2 has 2 PM teams with less than 4 employees
- AD staff currently detailed out of AD
  - Eric Miederhoff 1-year detail OECA ends March 2023– selected as RB BC
    - See above for backfilling with Tara
  - Karen Hicks detail to OCR continually extended
  - Joe Daniels (selected to PRD as Acting TL for 120 days)
  - Lindsay O'Dell selected for NAMs fellowship in OPPT for 6 mo

- **22** short of **103 FTE** level from approved 2020 reorganization (does not factor +14 for ideal state)
  - 8 of 22 reorganization FTE unfilled
  - 14 backfills unfilled
- 100% telework approvals for nearly 38% of AD (SharePoint [HYPERLINK "https://usepa.sharepoint.com/:x:/s/ocspp_Work/AD_IO/EQ5yYt16j6JFk38mhdtg7DQB0L4_-rYyn5T8bC1K_Iz28Q?email=Weiss.Steven%40epa.gov&e=KzznOc"])
  - 26 federal AD staff
  - 9 of AD's 11 SEE enrollees
- AD IO lost its only admin SEE enrollee
  - Will use PRD & BEAD's SEE enrollees for admin going fwd

Upcoming meetings/presentations/other

- HCPA Annual Meeting on 12/6

- OECD 6th Meeting of the Working Party on Biocides, September 27-28, relevant agenda topic: Item 4. Progress on the Best Practice Document on Management of Emergency Situations – Sylvie Poret will present the progress of the Best Practice Document since the Interim WPB meeting last year. This project aims to develop a document with best practices for use in a future pandemic and/or other emergency situation affecting the global biocide community.

Sales Force Metrics

- [HYPERLINK "https://oppt.lightning.force.com/lightning/r/Dashboard/01Z3d0000006mtUEAQ/view?queryScope=userFolders"]
- [HYPERLINK "https://oppt.lightning.force.com/lightning/r/Report/00O3d000000WPn5EAG/view?queryScope=userFolders"]